



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Richard Wolf Medical Instruments Corporation
Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, IL 60061

JUL 27 2015

Re: K020255

Trade/Device Name: RIWO NET Operating Control System Model #5590

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: ODA

Dated (Date on orig SE ltr): August 1, 2002

Received (Date on orig SE ltr): August 2, 2002

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of September 18, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

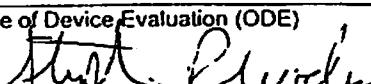
510(k) Number (if known): — K020255

Device Name: RIWO NET System 5590

Intended use: The RIWO NET SYSTEM 5590 is used for controlling an operating system by voice control, touch screen monitor or remote control unit in diagnostic and therapeutic endoscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020255

Prescription Use 
Per 21 CFR 801.109

OR

Over-The Counter



K020255
SEP 18 2002

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12.0 510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: January 22, 2002	
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.		FDA establishment registration number: 14 184 79	
Division name (if applicable): N.A.		Phone number (include area code): (847) 913 1113	
Street address: 353 Corporate Woods Parkway		FAX number (include area code): (847) 913 0924	
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: RIWO NET Operating Control System		Model number: 5590.xxx 32115.xxx	
Common name: Operating Control System RIWO NET, remote and voice control, CAN bus		Classification name: Endoscope and/or Accessories	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name		Manufacturer
1 K994231	1 SIEMENS Integrated Operating System (SIOS)		1 Siemens
2 K981993	2 EndoALPHA Integrated Endosurgery System		2 Olympus
3 K980787	3 HERMES Operating Room Control Center		3 Computer Motion
4	4 Operation Room Control OR1/ SCB PC		4 Karl Storz
5 K002328	5 SIOS-Interface for Light Projector, Camera, Insufflator		5 Richard Wolf



Ko.20255

1.0 Description

The RIWO NET System 5590 provides central user control of an endoscopic operating system using either voice or remote control from the sterile area or touch screen monitor. The RIWO NET System controls various endoscopy devices by uniform graphical user interface, such as light sources, cameras, insufflators, video recorders, etc.

2.0 Intended Use

The RIWO NET SYSTEM 5590 is used for controlling an operating system by voice control, touch screen monitor or remote control unit in diagnostic and therapeutic endoscopy.

3.0 Technological Characteristics

The connected endoscopy devices communicate via CAN bus / RS-232 interface. All the connected devices can always be controlled conventional with their buttons furthermore. When they are connected to the master RIWO NET System 5590, the RIWO NET controller recognized the new device automatically and after run-up period, the slave device can be used in the RIWO NET System.

The speech recognition is speaker independent. Various languages are available.

The complete RIWO NET System with endoscopy devices is placed in a mobile trolley.

4.0 Substantial Equivalence

The submitted devices are substantial equivalent to devices by Siemens, Olympus, Computer Motion, and Karl Storz. The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness.

5.0 Performance Data

The submitted devices are conforming to the international standards UL-2601-1, IEC60601-1 with A1 and A2, IEC 60601-1-1 with A1, IEC 60601-1-2.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By:

A handwritten signature in black ink, appearing to read "Robert L. Casarsa".

Robert L. Casarsa
Quality Assurance Manager

Date: Jan. 22, 2002.....